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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/705,625	11/03/2000	Xiu Xiu Cheng	300.1012	6705

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EXAMINER

WARE, TODD

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 12/31/2001

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/705,625

Applicant(s)

CHENG ET AL.

Examiner

Todd D Ware

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-- **Th MAILING DATE of this communication app ars on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 April 2001.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☒ Claim(s) 2 and 3 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

Receipt of declaration and fee filed 4-5-01 is acknowledged. Claims 1-34 are pending.

***Claim Objections***

1. Claims 2 and 3 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim: Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 1 requires a Tmax for metformin at 5.5 to 7.5 hours. Claim 2 broadens the scope of claim 1 to the class biguanides and claim 3 requires the active agent to be metformin, however, claim 1 already requires metformin.

***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
3. Claims 4-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4-31 require the method of claim 3, however claim 3 is a composition claim.

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4. Claims 22-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that they fail to point out what is included or excluded by the claim language. These claims are omnibus type claims.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

6. Claims 1-15, 19-34 are rejected under 35 U.S.C. 102(a) as being anticipated by Lewis et al (WO 00/28989; hereafter '989).

'989 discloses controlled release metformin compositions. '989 does not explicitly disclose the functional limitations of the instant claims, however since the formulations of '989 are substantially the same, it appears that the instant claimed functional limitations are inherent within '989. Therefore, the burden is shifted to applicants to demonstrate a difference between '989 and the instant claims (*In re Swinehart*, 169 USPQ 226 and *In re Fitzgerald* 205 USPQ 594).

7. Claims 1-15, 19-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Cheng et al (WO 99/47125; hereafter '125).

'125 discloses controlled release metformin compositions and is relied upon for the same reasons set forth in the previous 35 U.S.C. 102(a) rejections as being anticipated by Lewis et al (WO 00/28989; hereafter '989).

8. Claims 1-15, 19-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Moeckel et al (5,955,106; hereafter '106).

'106 discloses controlled release metformin compositions and is relied upon for the same reasons set forth in the previous 35 U.S.C. 102(a) rejections as being anticipated by Lewis et al (WO 00/28989; hereafter '989).

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lewis et al (WO 00/28989; hereafter '989) or Cheng et al (WO 99/47125; hereafter '125) or Moeckel et al (5,955,106; hereafter '106) each alone or each in combination with Drug Facts and Comparisons (1999).

'989, '125, and '106 all teach controlled release metformin compositions. They do not explicitly teach the functional limitations of the instant claims, however since the formulations of these references are substantially the same, it appears that the instant claimed functional limitations are inherent. Therefore, the burden is shifted to applicants to demonstrate a difference between the prior art and the instant claims (*In re Swinehart*, 169 USPQ 226 and *In re Fitzgerald* 205 USPQ 594). Varying amounts of ingredients, such as dose, or administration in two dosage forms would have been

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obvious to one skilled in the art at the time of the invention to provide a greater or lesser drug effect or, in the case of administration in two dosage forms, to administer a large dose in smaller tablets. '989, '125, and '106 do not teach the limitations of claims 16-17.

Drug Facts and Comparisons (DFC) is relied upon for teaching delivery of metformin in the presence or absence of food.

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to administer the compositions at dinner or at a fed state with the motivation of regulating sugar levels.

12. Claims 1-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al (6,270,805; hereafter '805) alone or in combination with Drug Facts and Comparisons (1999).

'805 discloses controlled release metformin compositions. '805 does not explicitly disclose some of the functional limitations of the instant claims, however since the formulations of '805 are substantially the same, it appears that the instant claimed functional limitations are inherent within '106. Therefore, the burden is shifted to applicants to demonstrate a difference between '106 and the instant claims (*In re Swinehart*, 169 USPQ 226 and *In re Fitzgerald* 205 USPQ 594). Varying amounts of ingredients, such as dose would have been obvious to one skilled in the art at the time of the invention to provide a greater or lesser drug effect.

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### ***Double Patenting***

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 1-34 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-29 of U.S. Patent No.

6,099,859. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are directed to limitations that are in a genus-species relationship and the functional limitations of the instant claims would be inherent in '859.

15. Claims 1-34 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-39 of U.S. Patent No.

6,284,275. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are directed to limitations that are in a genus-species relationship and the functional limitations of the instant claims would be

inherent in '275. Also, buformin is an adjacent homolog of metformin and therefore metformin is obvious over buformin.

16. Claims 1-34 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,099,862. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are directed to limitations that are in a genus-species relationship and the functional limitations of the instant claims would be inherent in '275.

17. Claims 1-34 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-42 of copending Application No. 09/705,630. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method claims disclose the compositions.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

18. Claims 1-34 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-29 of copending Application No. 09/726,193. Although the conflicting claims are not identical,

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they are not patentably distinct from each other because the method claims disclose the compositions.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

19. Claims 1-34 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-54 of copending Application No. 09/594,637. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method claims disclose the compositions.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd D Ware whose telephone number is (703) 305-1700. The examiner can normally be reached on M-F, 8:30 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703)308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

tw

December 21, 2001

THURMAN K. PAGE  
SENIOR PATENT EXAMINER  
703/308-1600